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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,786	05/17/2005	Halina Miller-Podraza	0933-0233PUS1	6363

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,786	MILLER-PODRAZA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-97* is/are pending in the application.

4a) Of the above claim(s) *68-81, 84, 91-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82,83,85-90 and 97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 21 July 2009, in which claim 82 is amended to change the scope and breadth of the claim and to place the claim in independent form, new claims 85-97 are added, and withdrawn claim 84 is amended.

This application is the national stage entry of PCT/FI03/00039, filed 20 Jan 2003; and claims benefit of foreign priority document PCT/FI02/00043, filed 18 Jan 2002; this foreign priority document is in English.

Claims 68-97 are pending in the current application. Claims 68-81 and 84 and new claims 91-96, drawn to non-elected inventions, are withdrawn. Claims 82, 83, 85-90 and 97 are examined on the merits herein.

Election/Restrictions

New claims 91- 96 are drawn the non-elected invention of Group IV, claim 84.

Applicant's traverse of the withdrawal of claim 84 and new claims 91-96 as drawn to an invention distinct from the elected invention in the reply filed on 21 July 2009 is acknowledged. The traversal is on the ground(s) that the method of claim 84 is dependent on the complex of *H pylori* with the oligosaccharide substance and not the oligosaccharide substance alone. This is not found persuasive because, as previously

recited, Lack of Unity of Invention is found because the common feature of the single general inventive concept of the inventions of Groups I-IV is deemed to be the *Helicobacter pylori* binding substance comprising a terminal oligosaccharide sequence, and said substance is a known product disclosed by Jacquinet et al. (US Patent 4,943,630, issued 24 Jul 1990, of record) and although Jacquinet et al. is silent as to the ability of the chemical composition to bind *Helicobacter pylori*, this property is necessarily present in the disclosed chemical structure that is identical to the instantly claimed structure.

The requirement is still deemed proper and is therefore made FINAL.

New Claims 91-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 24 Oct 2008.

Rejections Withdrawn

Applicant's Amendment, filed 21 July 2009, with respect to claims 82 and 83 are rejected under 35 U.S.C. § 112, first paragraph as not meeting the written description requirement has been fully considered and is persuasive, as amended claim 82 does not contain the specified language of claim 82 and claim 68.

This rejection has been **withdrawn**, however new grounds of rejection are made in view of the language of amended claim 82.

Applicant's Amendment, filed 21 July 2009, with respect to claims 82 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been fully considered and is persuasive, as amended claim 82 does not recite the method for the prevention of a condition due to or caused by the presence of *H. pylori*.

This rejection has been **withdrawn**.

Applicant's Remarks, filed 21 July 2009, with respect to claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crandall Jr. et al. (Proceedings of the Society for Experimental Biology and Medicine, 1933, 30, p704-706, cited in PTO-892) in view of the definition of chondroitin sulfuric acid (The Merck Index, 14th edition, cited in PTO-892) and in view of Kodama et al. (European Patent Application EP 1002805 A1, published 24 May 2000, cited in PTO-892) has been fully considered and is persuasive, as the Applicant is persuasive that the compound taught by Crandall does not unamibiguously teach chondroitin distinct from chondroitin sulfate, does not reasonably teach the terminal structure of chondroitin, and does not reasonably teach the ulcer treated within Crandall is caused by *H. pylori*.

This rejection has been **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 82, 88 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 82 recites "analogs or derivatives of said terminal oligosaccharide sequence having binding activity to Helicobacter pylori and comprising structures selected from the group consisting of: acetamido group mimicking group being another amide, amide derivatives from carboxylic acid group of the terminal uronic acid, or oligosaccharide structures having the same or similar conformations with said terminal oligosaccharide sequence". Claim 88 specifies the location of the derivatization but does not specify the type of derivative. Claim 97 depends from claim 82 and incorporates all limtations therein.

The specification discloses specific amide groups, such as amides from C1-C22 amines at page 8, lines 1-10 which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 82, 88, and 97 are directed to encompass amides, amides derivatives and oligosaccharide structures having similar conformations with said terminal oligosaccharide sequence, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these amides, amides derivatives and oligosaccharide structures having similar conformations with said terminal oligosaccharide sequence meet the written description requirement of

35 USC 112, first paragraph, due to lacking chemical structural information for what they are and because chemical amides, amides derivatives and oligosaccharide structures having similar conformations with said terminal oligosaccharide sequence are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification provides functional limitations as to the definition of derivatives and analogs at page 19, lines 20-30. It is unclear what genus is defined by the recitation "oligosaccharide structures having ... similar conformations with said terminal oligosaccharide sequence" because it is unclear what the metes and bounds of "similar" are.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 935 F.2d 1555, 1563 [19 USPQ2d 1111] (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*Vas-Cath* at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed amides, amides derivatives and oligosaccharide structures having similar conformations with said terminal oligosaccharide sequence, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere

statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. The court of *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 [43 USPQ2d 1398] (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The court of *In re Curtis*, 354 F.3d 1347 [69 USPQ2d 1274] (Fed. Cir. 2004) held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ... of any other species." The court of *Noelle v. Lederman,* 355 F.3d 1343 [69 USPQ2d 1508] (Fed. Cir. 2004) also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. The court of *Carnegie Mellon Univ. v. Hoffman-LaRoche Inc.*, 541 F.3d 1115, 1125 [88 USPQ2d 1233] (Fed. Cir. 2008) held that the written disclosure requirement was not met where the claims at issue covered a

broad "genus of recombinant plasmids that contain coding sequences for DNA polymerase ...from any bacterial source, [but] the narrow specifications of the[relevant patents] only disclose[d] the ... gene coding sequence from one bacterial source ...."

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description requirement of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that *Vas-Cath* makes clear that the written description requirement of 35 USC 112 is severable from its enablement provision. (See *Vas-Cath* at page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 82, 83, 85-90 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 recites administering a pharmaceutically effective amount of a *Helicobacter pylori* binding substance, said substance comprising a terminal oligosaccharide sequence. Claims 83, 85-90 and 97 depend from claim 82 and incorporate all limitations therein.

Claim 82 requires administering a pharmaceutically effective amount of said substance presented as a partial structure. MPEP 2173.05(t) provides "claim to a chemical compound is not indefinite merely because a structure is not presented or

because a partial structure is presented" and "A compound of unknown structure may be claimed by a combination of physical and chemical characteristics". However, the instant claims are drawn to a pharmaceutically effective amount of said substance. The specification at page 1-2 disclosing the background in the art provides that the pharmaceutical function of the administered compound is by binding of *Helicobacter pylori*. It is well known in the art that the pharmaceutically effective amount of a substance will depend on the activity of said substance and the activity of said substance will be related to the structure of said substance. The instant claim, drawn to a method of administering a pharmaceutically effective amount of said substance, is indefinite because, absent a limitation identifying the entire structure of the compound, one of skill in the art would not be readily apprised of the metes and bounds of the claim because one of skill in the art would not be able to determine the pharmaceutically effective amount of the compound presented as a partial structure.

Conclusion

No claim is found to be allowable.

This Office Action details new grounds of rejection not necessitated by Applicant's Amendment. Accordingly, this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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